



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

OCT -9 2002

NADA 140-971

Rosalind S. Dunn  
Director, Regulatory Affairs  
Merial Ltd.  
3239 Satellite Blvd.  
Duluth, GA 30096

Dear Ms. Dunn:

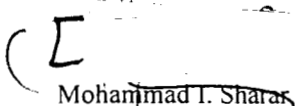
We refer to several of your advertisements for Heartgard Plus (ivermectin/pyrantel) for Dogs, NADA 140-971, that have come to our attention. The four advertisements in question for Heartgard Plus appeared in the February 2002 issue of *Veterinary Forum*. The pieces are entitled: "Better for Them, Better for You" (HGD-2-1002, 4.86-TVJ), "Give new puppy owners 6 fewer things to worry about" (HGD-2-1002, 4.43-TVJ), "Internal parasite protection is not a one-shot deal" (HGD-2-1002, 4.14-TVJ), and "Don't take chances with parasite protection" (HGD-2-1002, 4.15-TVJ). These items all contain various drug claims for Heartgard Plus and are deemed to be advertisements under 21 CFR 202.1 (I)(1).

The materials listed above are in violation of 21 CFR 202.1 (e)(5)(ii) in that they fail to present fair balance within the body of the promotional text between information relating to side effects and contraindications in comparable depth and detail with the claims for the effectiveness and safety provided in the approved labeling. Specifically, the pieces fail to include important adverse drug reaction information in the approved labeling relating to depression/lethargy, anorexia, mydriasis, ataxia, staggering, convulsions, and hypersalivation. The omission of this information is also in violation of 21 CFR 202.1(e)(3)(iii).

We wish to remind you of the commitment you made when you signed the New Animal Drug Application Form, FDA 356V, that you will promote your product only in accord with the labeling provided in the currently approved application.

We request that you immediately stop using these violative advertisements and in the future include both risk and the benefit information in a fairly balanced manner in all of your advertisements. Please inform us of your intentions as possible or in any event within 30 days of the receipt date of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours,

  
Mohammad I. Sharaf, DVM, M.Sc.  
Team Leader, Marketed Product Scientific  
and Regulatory Review Team II, HFV-216  
Division of Surveillance  
Center for Veterinary Medicine